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09/721,114	11/22/2000	Hirohiko Hirochika	MAFF-1	2997

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/721,114	Applicant(s) HIROCHIKA ET AL.	
	Examiner Juliet C Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 5/22/02, paper number 8. Claims 1-3 have been amended. Claims 1-3 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Drawings

2. The drawings are approved for examination.

Claim Rejections - 35 USC § 101

3. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

Claims 1-3 are drawn to polynucleotides encoding a plant gene capable of controlling a signal transduction system for brassinosteroid hormone. The specification asserts that these polynucleotides are of use in plant breeding (p. 14). Specifically, the specification teaches that "by introducing the present polynucleotide into plants and artificially controlling various effects in which the brassinosteroid hormone is involved, it is expected that effects such as growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." However, beyond this assertion, the specification does not provide any guidance or evidence that such effects can be achieved in plants. The specification does not provide any evidence that the instant polypeptide is even able

to control a signal transduction system for brassinosteroid hormone. In example 6, applicant demonstrates that wild type and mutant type rice plants respond differently to a brassinolide steroid, and assumes that it is the presence of a mutated form of instant SEQ ID NO: 2 causing such a response, but Applicant has not provided any evidence of such a causative relationship. In order to utilized the instant invention, further experimentation would be necessary to reasonably confirm the activity of the claimed polynucleotides. In genetically modified plants, the introduced transgenes are sometimes not expressed, and they can also result in co-suppression effects. None of these effects are predictable, and the mechanisms of gene silencing are still not fully understood. Thus, success in modification of gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable and hence significant guidance is required to practice the art without undue experimentation. Moreover, the phenotypic characteristics that will result from expression of a given DNA construct cannot be reliably predicted. In fact, often the expected phenotypic result is not achieved. Thus, in light of the instant disclosure, the proposed utility is not considered to be substantial because further experimentation would be necessary to reasonably confirm a use for the claimed polynucleotides.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would

require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejections - 35 USC § 112

4. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to polynucleotides encoding a plant gene capable of controlling a signal transduction system for brassinosteroid hormone, the polynucleotide encoding SEQ ID NO: 2, including any polynucleotide encoding an amino acid sequence in with at least 80% homology to SEQ ID NO: 2. Claim 2 indicates that the polynucleotide is from rice. In light of the inclusion at the end of claim 1 indicating that the claimed polynucleotide includes any polynucleotide encoding an amino acid sequence that is largely altered as compared to SEQ ID NO: 2, allowing for changes in over 200 different amino acids. The claim is limited to encompass only polynucleotides encoding polypeptides that "controls a signal transduction

system for brassinosteroid hormone." However, this functional limitation is quite broad in nature. In this case the function recited in the specification is not associated with any particular structure. A polypeptide that "controls a signal transduction system for brassinosteroid hormone" could be a protein that interacts with transcription factors, it could be a hormone receptor, it could be the hormones themselves. Thus, the functional limitation provided in instant claim 1 is quite broad in nature.

The specification teaches only a single amino acid sequence, SEQ ID NO: 2, and the cDNA (SEQ ID NO: 1) and genomic DNA (SEQ ID NO: 3) encoding SEQ ID NO: 2. Thus, applicant has express possession of only one species in a genus which comprises hundreds of millions of different possibilities. Applicant has not described any variants of SEQ ID NO: 2, nor any polynucleotides which encode variants of SEQ ID NO: 2. For example, the prior art (Sasaki *et al.*) provides a polynucleotide encoding a hypothetical protein which comprises instant SEQ ID NO: 2 but also has an additional 328 amino acids upstream of SEQ ID NO: 2 (see Appendix 1). It is not clear if the polypeptide encoded by the nucleic acid taught by Sasaki *et al.* is the full length version of the instantly disclosed polypeptide or a variant of the instantly disclosed polypeptide. In either situation, Applicant's instant claim encompass polynucleotides such as those taught by Sasaki *et al.*, yet applicant has not demonstrated possession of such polynucleotides.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 1-2 include modifications by permitted by deletion, substitution, or addition yet still retaining 80%

homology to SEQ ID NO: 2 for which no written description is provided in the specification. Applicant has provided no guidance as to how or where the instantly disclosed polypeptides and polynucleotides can be modified yet still retain their claimed functionality.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the sequences of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids encoding proteins modified by addition, insertion, deletion, substitution or inversion with respect to the disclosed SEQ ID No: 2 such that a different amino acid sequence is encoded which retains the ability to control a signal transduction system for brassinosteroid hormone.

Claim Rejections - 35 USC § 112

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are further indefinite because claim 1 appears to have conflicting limitations. On the one hand, the claim requires that the claimed polynucleotides encode an amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2, yet on the other hand, the claim includes any polynucleotide encoding an amino acid sequence with at least 80% homology to SEQ ID NO: 2. Thus, it is unclear if the claim reads only on polynucleotides which encode SEQ ID NO: 2, or if the claim is broader such that it reads on any polynucleotide that encodes a polypeptide that has the recited function of controlling a signal transduction system for brassinosteroid hormone and also has 80% identity to SEQ ID NO: 2. Amendment of the claim to read, for example, "...in the SEQUENCE LISTING, or any polynucleotide encoding an amino acid sequence with at least 80% homology to SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. No foreign priority documents have been received as of the writing of this office action.

8. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Sasaki *et al.* (GenBank Accession AP001859, 27 May 2000) OR Sasaki *et al.* (EMBL Accession AP001859, 20 April 2000).

Sasaki *et al.* provide a polynucleotide which is the Oryza sativa genomic DNA, chromosome 1. Sasaki et al. teach an isolated polynucleotide encoding a plant polypeptide, the polynucleotide encoding an amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2. Applicant's attention is directed to the 8th coding sequence predicted by Sasaki *et al.*, beginning at nucleotide 46467. Instant SEQ ID NO: 2 is contained within the translation product of this coding sequence. Amino acids 1-1057 of instant SEQ ID NO: 2 are identical to amino acids 329-1385 of the predicted translation product. In the nucleic acid sequence taught by Sasaki *et al.*, the start codon for SEQ ID NO: 2 begins at nucleotide 52820 of the sequence taught by Sasaki *et al.* The final ARG of SEQ ID NO: 2 is encoded at nucleotide 57465 of the sequence taught by Sasaki *et al.*

Applicant has been provided with two different copies of the sequence disclosure provided by Sasaki *et al.* The "creation date" for an EMBL record is the date of public availability. Thus, for the EMBL record, the creation date is 20 April 2000. The GenBank record is dated 27 May 2000. In the interest of being thorough, both copies have been provided for applicant's review.

Response to Remarks

In response to the 101 utility rejection and the 112 1st paragraph lack of enablement rejection, applicant traverses the examiner's assertion that the specification does not provide evidence of a causative relationship between the presence of the mutated form of the claimed

polynucleotide and an altered response to brassinosteroid hormone. Applicant points to the examples in the specification which demonstrate that the claimed gene is expressed in all organs of the plant and describes sequence motifs consistent with involvement in signal transduction. However, even in light of these examples, as discussed in the rejection, applicant has not shown a causative relationship between the lack of response to the brassinolide and the mutation in the instant polypeptide. Applicant has merely shown that the mutated polypeptide is associated with the lack of response (i.e. diagnostic of) and not in fact necessarily causative. Applicant has inferred the causative relationship and then further provided a list of speculative utilities based on this inference. The instant specification provides a list of possible effects that may be achieved by transforming plants with the claimed polynucleotides, including "growth promotion, yield increase, quality improvement, maturation enhancement, and tolerance against biotic and abiotic stresses can be controlled... (p. 14)." This listing constitutes an invitation for one to undertake further experimentation to reasonably confirm that such effects could be achieved by using the instant polynucleotides. The general designation in this case that the polypeptide encoded by the instant polynucleotides in active in a particular pathway does not clearly define the actual utility of this polypeptide, it merely suggests, as applicant did in the specification that certain effects may possibly be achieved using this polypeptide, thus inviting one to attempt further experiments to in fact determine if these effects can be achieved.

Applicant spends some time discussing the essential role of brassinosteroids in plants. The examiner is not questioning the role of brassinosteroids in plants, but is asserting that a substantial utility does not exist for a polypeptide that is merely thought to be active in a the control pathway for brassinosteroids. Finally, applicant asserts that the specification teaches that

brassinosteroid hormone agricultural chemicals are used to achieve agriculturally useful effects. This is correct, and the specification further asserts that the instant polypeptide can be used to "provide a number of agriculturally useful effects as are attained by treatments with brassinosteroid hormone agricultural chemicals." However, again, this is merely an invitation to the reader to undertake further experimentation to confirm that such effects are possible, and thus, this asserted utility is not considered substantial. For these reasons, the rejections are maintained.

The rejection under 112 1st paragraph for lack of written description has been modified to respond to applicant's amendments to the claims. Applicant asserts that the claims are fully described because one could determine the homology of other sequences using software programs. However, this is not sufficient to demonstrate that applicant was in possession of all nucleic acids encoding polypeptides with at least 80% homology to SEQ ID NO: 2 and functional in the control of the brassinosteroid pathway. As discussed in the rejection, the types and sequences of polypeptides that could be active in the control of brassinosteroid hormone signal transduction is widely varied, thus, the functional language of the claim encompasses many, many different types polypeptides. Furthermore, the specification does not provide any guidance as to how or where instant SEQ ID NO: 2 can be modified and still retain its essential function of being active in the control of brassinosteroid hormone signal transduction. Thus, even in light of the amended claims, this rejection is maintained.

Applicant argues that the amendment to claim 1 obviates the examiner's rejection to conflicting limitations to the claims. However, the rejection is maintained because the conflict exists with the new wording of the claim. The language of claim 1 "the polynucleotide encoding

an amino acid sequence from Met at position 1 to Arg at position 1057 of SEQ ID NO: 2" appears to require that the nucleic acid that meets this limitation encodes those precise amino acids recited in SEQ ID NO: 2. But then, the claim further states "including any polynucleotide encoding an amino acid sequence with at least 80% homology to SEQ ID NO: 2" which is a much broader recitation. Thus, applicant is indicating that a broader recitation is included within a narrower limitation and this is indefinite and confusing. The rejection is therefore modified herein to be relevant to the amended claims.

Applicant points out that the sequence described by Sasaki et al. is identified only as Oryza sativa genomic DNA, chromosome 1, and that the predicted coding sequence pointed out by the examiner is substantially larger than the polypeptide encoded by the polynucleotide of amended claims 1-3. The examiner disagrees. The isolated polynucleotide taught by Sasaki et al. is within the metes and bounds of instant claims 1-3. Instant claim 1 encompasses any and all nucleic acids that would encode instant SEQ ID NO: 2. The genomic DNA provided by Sasaki et al. clearly encodes SEQ ID NO: 2, as is particularly evident by the fact that Sasaki et al. predict this coding sequence, albeit within a larger sequence. The fact that Sasaki et al. did not know that this polypeptide may be active in a signal transduction system for brassinosteroid hormone is irrelevant to the fact that the polypeptide is inherently genomic DNA that encodes SEQ ID NO: 2. Sasaki et al. has not been applied to amended claim 3 because amended claim 3 has been amended to recite that the claimed nucleic acid comprises instant SEQ ID NO: 1. Neither the genomic DNA nor the coding sequence provided by Sasaki et al. comprises instant SEQ ID NO: 1, although the coding sequence taught by Sasaki et al. in the comments of the record comprises the entire portion of SEQ ID NO: 1 beginning at nucleotide 629 until the end.

Because Sasaki et al. teach a different predicted coding sequence from that provided in the instant application, claim 3 is free of the prior art.

Applicant submitted a certified copy of a foreign priority document in Japanese, pointing out that the sequence listing is in English. However, in order to evaluate the priority document for support of claim 1 in its entirety, a full translation of the priority document is required to perfect priority and overcome the May 27, 2000 Sasaki et al. reference.

For these reasons, all of the reiterated rejections are maintained.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824.

The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C Einsmann
Examiner
Art Unit 1634

August 8, 2002